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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/808,124	03/15/2001	Robert Jason Potter	0942.5030001/RWE	4601

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EXAMINER

STRZELECKA, TERESA E

ART UNIT	PAPER NUMBER
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1656

16

DATE MAILED: 01/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/808,124

Applicant(s)

POTTER ET AL.

Examiner

Teresa E Strzelecka

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-62 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-62 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____

DETAILED ACTION

Election/Restrictions

6. Prior to setting forth the Restriction Requirement, it is pointed out that applicants have presented claims 1-24, 32-41, 47-52, 60-62 in improper format. The claims are improperly joined as the various groups indicated below appear to encompass distinct inventions (polypeptides with different functions and amino acid sequences) to such an extent that they are considered separately patentable. Therefore, the restriction will be set forth for each of the various groups, irrespective of the improper format of the claims, because these are not proper species.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1 (a) (in part), 2 (in part), 9 (in part), 11-22, 25-28 (all in part), 32, 47-52 (all in part), drawn to an M-MLV reverse transcriptase which has been modified or mutated to increase or enhance fidelity, classified in class 435, subclass 183.
- II. Claims 1 (a) (in part), 2 (in part), 9 (in part), 24, 25-28 (all in part), 32, 47-52 (all in part), drawn to an RSV reverse transcriptase which has been modified or mutated to increase or enhance fidelity, classified in class 435, subclass 183.
- III. Claims 1 (a) (in part), 2 (in part), 9 (in part), 23, 25-28 (all in part), 32, 47-52 (all in part), drawn to an AMV reverse transcriptase which has been modified or mutated to increase or enhance fidelity, classified in class 435, subclass 183.
- IV. Claims 1 (b) (in part), 3 (in part), 9 (in part), 29-31 (all in part), 47-52 (all in part), drawn to an M-MLV reverse transcriptase which has been modified or mutated to reduce or eliminate misincorporation of nucleotides during nucleic acid synthesis, classified in class 435, subclass 183.

- V. Claims 1 (b) (in part), 3 (in part), 9 (in part), 29-31 (all in part), 47-52 (all in part), drawn to an RSV reverse transcriptase which has been modified or mutated to reduce or eliminate misincorporation of nucleotides during nucleic acid synthesis, classified in class 435, subclass 183.
- VI. Claims 1 (b) (in part), 3 (in part), 9 (in part), 29-31 (all in part), 47-52 (all in part), drawn to an AMV reverse transcriptase which has been modified or mutated to reduce or eliminate misincorporation of nucleotides during nucleic acid synthesis, classified in class 435, subclass 183.
- VII. Claims 1 (c) (in part), 4 (in part), 9 (in part), 33, 34-39, 42-52 (all in part), drawn to an M-MLV reverse transcriptase which has been modified or mutated to decrease or eliminate terminal deoxynucleotidyl transferase activity, classified in class 435, subclass 183.
- VIII. Claims 1 (c) (in part), 4 (in part), 9 (in part), 41, 42-52 (all in part), drawn to an RSV reverse transcriptase which has been modified or mutated to decrease or eliminate terminal deoxynucleotidyl transferase activity, classified in class 435, subclass 183.
- IX. Claims 1 (c) (in part), 4 (in part), 9 (in part), 40, 42-52 (all in part), drawn to an AMV reverse transcriptase which has been modified or mutated to decrease or eliminate terminal deoxynucleotidyl transferase activity, classified in class 435, subclass 183.
- X. Claims 1 (a) (in part), 1 (b) (in part) and 5, drawn to a reverse transcriptase which has been modified or mutated to increase or enhance fidelity and to reduce or eliminate misincorporation of nucleotides during nucleic acid synthesis, classified in class 435, subclass 183.

- XI. Claims 1 (a) (in part), 1 (c) (in part) and 6, drawn to a reverse transcriptase which has been modified or mutated to increase or enhance fidelity and to decrease or eliminate terminal deoxynucleotidyl transferase activity, classified in class 435, subclass 183.
- XII. Claims 1 (b) (in part), 1 (c) (in part) and 7, drawn to a reverse transcriptase which has been modified or mutated to reduce or eliminate misincorporation of nucleotides during nucleic acid synthesis and to decrease or eliminate terminal deoxynucleotidyl transferase activity, classified in class 435, subclass 183.
- XIII. Claims 1 (a), 1 (b) and 1 (c) (all in part), drawn to a reverse transcriptase which has been modified or mutated to increase or enhance fidelity and to reduce or eliminate misincorporation of nucleotides during nucleic acid synthesis and to decrease or eliminate terminal deoxynucleotidyl transferase activity, classified in class 435, subclass 183.
- XIV. Claims 1 (a), 2, 8 and 10 (all in part), drawn to an M-MLV reverse transcriptase with substantially reduced RNase H activity which has been modified or mutated to increase or enhance fidelity, classified in class 435, subclass 183.
- XV. Claims 1 (a), 2, 8 and 10 (all in part), drawn to an RSV reverse transcriptase with substantially reduced RNase H activity which has been modified or mutated to increase or enhance fidelity, classified in class 435, subclass 183.
- XVI. Claims 1 (a), 2, 8 and 10 (all in part), drawn to an AMV reverse transcriptase with substantially reduced RNase H activity which has been modified or mutated to increase or enhance fidelity, classified in class 435, subclass 183.

- XVII. Claims 1 (a), 2, 8 and 10 (all in part), drawn to a RAV reverse transcriptase with substantially reduced RNase H activity which has been modified or mutated to increase or enhance fidelity, classified in class 435, subclass 183.
- XVIII. Claims 1 (b), 2, 8 and 10 (all in part), drawn to an M-MLV reverse transcriptase with substantially reduced RNase H activity which has been modified or mutated to reduce or eliminate misincorporation of nucleotides during nucleic acid synthesis, classified in class 435, subclass 183.
- XIX. Claims 1 (b), 2, 8 and 10 (all in part), drawn to an RSV reverse transcriptase with substantially reduced RNase H activity which has been modified or mutated to reduce or eliminate misincorporation of nucleotides during nucleic acid synthesis, classified in class 435, subclass 183.
- XX. Claims 1 (b), 2, 8 and 10 (all in part), drawn to an AMV reverse transcriptase with substantially reduced RNase H activity which has been modified or mutated to reduce or eliminate misincorporation of nucleotides during nucleic acid synthesis, classified in class 435, subclass 183.
- XXI. Claims 1 (b), 2, 8 and 10 (all in part), drawn to a RAV reverse transcriptase with substantially reduced RNase H activity which has been modified or mutated to reduce or eliminate misincorporation of nucleotides during nucleic acid synthesis, classified in class 435, subclass 183.
- XXII. Claims 1 (c), 2, 8 and 10 (all in part), drawn to an M-MLV reverse transcriptase with substantially reduced RNase H activity which has been modified or mutated to decrease or eliminate terminal deoxynucleotidyl transferase activity, classified in class 435, subclass 183.

- XXIII. Claims 1 (c), 2, 8 and 10 (all in part), drawn to an RSV reverse transcriptase with substantially reduced RNase H activity which has been modified or mutated to decrease or eliminate terminal deoxynucleotidyl transferase activity, classified in class 435, subclass 183.
- XXIV. Claims 1 (c), 2, 8 and 10 (all in part), drawn to an AMV reverse transcriptase with substantially reduced RNase H activity which has been modified or mutated to decrease or eliminate terminal deoxynucleotidyl transferase activity, classified in class 435, subclass 183.
- XXV. Claims 1 (c), 2, 8 and 10 (all in part), drawn to a RAV reverse transcriptase with substantially reduced RNase H activity which has been modified or mutated to decrease or eliminate terminal deoxynucleotidyl transferase activity, classified in class 435, subclass 183.
- XXVI. Claims 1 (a), 1 (b), 2, 8 and 10 (all in part), drawn to an M-MLV reverse transcriptase with substantially reduced RNase H activity which has been modified or mutated to increase or enhance fidelity and to reduce or eliminate misincorporation of nucleotides during nucleic acid synthesis, classified in class 435, subclass 183.
- XXVII. Claims 1 (a), 1 (b), 2, 8 and 10 (all in part), drawn to an RSV reverse transcriptase with substantially reduced RNase H activity which has been modified or mutated to increase or enhance fidelity and to reduce or eliminate misincorporation of nucleotides during nucleic acid synthesis, classified in class 435, subclass 183.

- XXVIII. Claims 1 (a), 1 (b), 2, 8 and 10 (all in part), drawn to an AMV reverse transcriptase with substantially reduced RNase H activity which has been modified or mutated to increase or enhance fidelity and to reduce or eliminate misincorporation of nucleotides during nucleic acid synthesis, classified in class 435, subclass 183.
- XXIX. Claims 1 (a), 1 (b), 2, 8 and 10 (all in part), drawn to a RAV reverse transcriptase with substantially reduced RNase H activity which has been modified or mutated to increase or enhance fidelity and to reduce or eliminate misincorporation of nucleotides during nucleic acid synthesis, classified in class 435, subclass 183.
- XXX. Claims 1 (a), 1 (c), 2, 8 and 10 (all in part), drawn to an M-MLV reverse transcriptase with substantially reduced RNase H activity which has been modified or mutated to increase or enhance fidelity and to decrease or eliminate terminal deoxynucleotidyl transferase activity, classified in class 435, subclass 183.
- XXXI. Claims 1 (a), 1 (c), 2, 8 and 10 (all in part), drawn to an RSV reverse transcriptase with substantially reduced RNase H activity which has been modified or mutated to increase or enhance fidelity and to decrease or eliminate terminal deoxynucleotidyl transferase activity, classified in class 435, subclass 183.
- XXXII. Claims 1 (a), 1 (c), 2, 8 and 10 (all in part), drawn to an AMV reverse transcriptase with substantially reduced RNase H activity which has been modified or mutated to increase or enhance fidelity and to decrease or eliminate terminal deoxynucleotidyl transferase activity, classified in class 435, subclass 183.
- XXXIII. Claims 1 (a), 1 (c), 2, 8 and 10 (all in part), drawn to a RAV reverse transcriptase with substantially reduced RNase H activity which has been modified

or mutated to increase or enhance fidelity and to decrease or eliminate terminal deoxynucleotidyl transferase activity, classified in class 435, subclass 183.

XXXIV. Claims 1 (b), 1 (c), 2, 8 and 10 (all in part), drawn to an M-MLV reverse transcriptase with substantially reduced RNase H activity which has been modified or mutated to reduce or eliminate misincorporation of nucleotides during nucleic acid synthesis and to decrease or eliminate terminal deoxynucleotidyl transferase activity, classified in class 435, subclass 183.

XXXV. Claims 1 (b), 1 (c), 2, 8 and 10 (all in part), drawn to an RSV reverse transcriptase with substantially reduced RNase H activity which has been modified or mutated to reduce or eliminate misincorporation of nucleotides during nucleic acid synthesis and to decrease or eliminate terminal deoxynucleotidyl transferase activity, classified in class 435, subclass 183.

XXXVI. Claims 1 (b), 1 (c), 2, 8 and 10 (all in part), drawn to an AMV reverse transcriptase with substantially reduced RNase H activity which has been modified or mutated to reduce or eliminate misincorporation of nucleotides during nucleic acid synthesis and to decrease or eliminate terminal deoxynucleotidyl transferase activity, classified in class 435, subclass 183.

XXXVII. Claims 1 (b), 1 (c), 2, 8 and 10 (all in part), drawn to a RAV reverse transcriptase with substantially reduced RNase H activity which has been modified or mutated to reduce or eliminate misincorporation of nucleotides during nucleic acid synthesis and to decrease or eliminate terminal deoxynucleotidyl transferase activity, classified in class 435, subclass 183.

- XXXVIII. Claims 1 (a), 1 (b), 1 (c), 2, 8 and 10 (all in part), drawn to an M-MLV reverse transcriptase with substantially reduced RNase H activity which has been modified or mutated to increase or enhance fidelity and to reduce or eliminate misincorporation of nucleotides during nucleic acid synthesis and to decrease or eliminate terminal deoxynucleotidyl transferase activity, classified in class 435, subclass 183.
- XXXIX. Claims 1 (a), 1 (b), 1 (c), 2, 8 and 10 (all in part), drawn to an RSV reverse transcriptase with substantially reduced RNase H activity which has been modified or mutated to increase or enhance fidelity and to reduce or eliminate misincorporation of nucleotides during nucleic acid synthesis and to decrease or eliminate terminal deoxynucleotidyl transferase activity, classified in class 435, subclass 183.
- XL. Claims 1 (a), 1 (b), 1 (c), 2, 8 and 10 (all in part), drawn to an AMV reverse transcriptase with substantially reduced RNase H activity which has been modified or mutated to increase or enhance fidelity and to reduce or eliminate misincorporation of nucleotides during nucleic acid synthesis and to decrease or eliminate terminal deoxynucleotidyl transferase activity, classified in class 435, subclass 183.
- XLI. Claims 1 (a), 1 (b), 1 (c), 2, 8 and 10 (all in part), drawn to a RAV reverse transcriptase with substantially reduced RNase H activity which has been modified or mutated to increase or enhance fidelity and to reduce or eliminate misincorporation of nucleotides during nucleic acid synthesis and to decrease or

eliminate terminal deoxynucleotidyl transferase activity, classified in class 435, subclass 183.

XLII. Claims 53-57, drawn to a method of reverse transcription of nucleic acid and the cDNA products, classified in class 435, subclass 91.1 and in class 536, subclass 23.1.

XLIII. Claims 58 and 60, drawn to a method of amplifying nucleic acid molecules using reverse transcriptase(s) and DNA polymerase(s), and a kit comprising one or more reverse transcriptases, classified in class 435, subclass 91.1 and in class 435, subclass 810.

XLIV. Claims 59, 61 and 62, drawn to a method of sequencing nucleic acid molecules using reverse transcriptase(s), primers and terminating agents, and a kit comprising one or more reverse transcriptases, classified in class 435, subclass 91.1 and in class 435, subclass 810.

The inventions are distinct, each from the other because of the following reasons:

3. Inventions I-XLI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are reverse transcriptases which are different entities with different functions and different modes of operation.

4. Inventions I-XLI and XLII-XLIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)).

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In the instant case the methods could be practiced using an entirely different product, such as an HIV reverse transcriptase.

5. Inventions XLII-XLIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to methods which have different method steps, starting materials and goals.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E Strzelecka whose telephone number is (703) 306-5877. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at (703) 308-1152. The fax phone numbers for the organization

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where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

TS
January 2, 2002

TS

Kenneth R. Horlick
KENNETH R. HORLICK
PRIMARY EXAMINER
GROUP 1600 1/3/02